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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,912	01/11/2001	David G. O'Dowd	2501.1004-001	9287
21005	7590	01/10/2005	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			NAJARIAN, LENA	
		ART UNIT	PAPER NUMBER	
		3626		

DATE MAILED: 01/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/758,912	O'DOWD, DAVID G.	
	Examiner	Art Unit	
	Lena Najarian	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 11 January 2001.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) 'Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-9 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because its length is less than 50 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 2 recites the limitation "the destruction" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

5. Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of:

- (1) whether the invention is within the technological arts; and
- (2) whether the invention produces a useful, concrete, and tangible result.

For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory subject matter. For a process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts.

(A) In the present case, claims 1-3 only recite an abstract idea. The recited steps of exemplary claim 1 of merely collecting one or more samples from a subject, providing a sample associated with a first code to a researcher, providing personal information to a third party, and providing a second code to the researcher does not apply, involve, use, or advance the technological arts since all of the recited steps can be performed in the mind of the user or by use of a pencil and paper.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case, the claimed invention produces a method for anonymizing samples for use in research and

development activities. Although the recited process produces a useful, concrete, and tangible result, since the claimed invention, as a whole, is not within the technological arts as explained above, claims 1-3 are deemed to be directed to non-statutory subject matter.

(B) In the present case, claims 4-6 only recite an abstract idea. The recited steps of exemplary claim 4 of merely collecting a sample and sample information from a subject, providing the sample information and personal information to a third party, and providing the sample and sample information to a researcher does not apply, involve, use, or advance the technological arts since all of the recited steps can be performed in the mind of the user or by use of a pencil and paper.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case, the claimed invention produces a method for anonymizing samples for use in research and development activities. Although the recited process produces a useful, concrete, and tangible result, since the claimed invention, as a whole, is not within the technological arts as explained above, claims 4-6 are deemed to be directed to non-statutory subject matter.

(C) In the present case, claims 7-9 only recite an abstract idea. The recited steps of exemplary claim 7 of merely providing a request for a sample, soliciting the sample, collecting and then submitting the sample, sample information, and personal information to the third party, associating a code with the sample, sample information, and personal information, submitting the sample and sample information to the researcher, and

storing the personal information does not apply, involve, use, or advance the technological arts since all of the recited steps can be performed in the mind of the user or by use of a pencil and paper.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case, the claimed invention produces a method for anonymizing samples for use in research and development activities. Although the recited process produces a useful, concrete, and tangible result, since the claimed invention, as a whole, is not within the technological arts as explained above, claims 7-9 are deemed to be directed to non-statutory subject matter.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Beecham (5,876,926).

(A) Referring to claim 1, Beecham discloses a method for anonymizing samples for use in research and development activities, the method comprising (abstract, lines 1-3 of Beecham):

- (a) collecting one or more samples from a subject by an investigator site (abstract, lines 1-5 of Beecham);
- (b) providing a sample to a researcher by the investigator site, wherein the sample is associated with a first code (col. 4, lines 44-46 of Beecham);
- (c) providing personal information to a third party by the investigator site, wherein the personal information is sufficient to link the subject with the one or more samples (col. 4, lines 30-43 & 52-63 of Beecham); and
- (d) providing a second code to the researcher by the third party (col. 11, lines 18-36 of Beecham; the Examiner interprets "biometric indicia" to be a form of "second code").

(B) Referring to claim 2, Beecham discloses wherein the method comprises the additional step of the destruction of the personal information (col. 24, lines 7-23 of Beecham; the Examiner interprets "photograph or home address" to be forms of "personal information").

(C) Referring to claim 3, Beecham discloses wherein the samples are to be used in a longitudinal study (col. 4, lines 44-51 and col. 17, lines 7-28 of Beecham; the Examiner interprets "follow-up" to be a form of "longitudinal study").

(D) Referring to claim 4, Beecham discloses a method for anonymizing samples for use in research and development activities, the method comprising (abstract, 1-3 of Beecham):

- (a) collecting from a subject by an investigator site:
 - (i) a sample (abstract, lines 1-5 of Beecham); and

(ii) sample information (col. 1, lines 47-49 of Beecham ; the Examiner interprets "relevant medical records" to be a form of "sample information");

(b) providing to a third party by the investigator site:

(i) the sample information of (a)(ii) (col. 1, lines 47-49 of Beecham); and

(ii) personal information sufficient to link the subject of (a) with the

sample of (a)(i) and the sample information of (a)(ii) (col. 4, lines 32-43 of Beecham);

(c) providing the sample of (a)(i) to a researcher by the investigator site, wherein the sample is associated with a first code (col. 4, lines 44-46 of Beecham); and

(d) providing to the researcher by the third party the sample information of (a)(ii), wherein the sample information is associated with a second code (abstract, lines 7-13 and col. 4, lines 44-46; the Examiner interprets "biometric data" to be a form of "second code").

(E) Referring to claim 5, Beecham discloses further comprising the steps of:

(e) providing to the third party by the researcher:

(i) the first code; and

(ii) a request for one or more samples of the subject associated with

the first code (col. 4, lines 32-51 of Beecham; the Examiner interprets "unique identifying code or serial number" to be a form of "first code"); and

(f) taking a sample from the subject by the third party, wherein the sample is associated with the first code of (e), and providing the sample to the researcher (col. 4, lines 32-47 of Beecham).

(F) Referring to claim 6, Beecham discloses further comprising the steps of:

(e) providing to the third party by the researcher:

(i) the second code (col. 11, lines 22-33 of Beecham; the Examiner interprets

“biometric indicia” to be a form of “second code”); and

(ii) a request for one or more samples of the subject associated with

the second code (col. 4, lines 44-51 of Beecham); and

(f) taking a sample from the subject associated with the second code of (e), wherein the sample is taken by the third party and provided to the researcher (col. 4, lines 32-47 and col. 7, lines 34-48 of Beecham).

(G) Referring to claim 7, Beecham discloses a method for anonymizing samples for use in research and development activities, the method comprising:

(a) providing a request for a sample by a researcher to a third party;

(b) soliciting the sample from one or more investigator sites wherein the soliciting is done by the third party (col. 4, lines 32-51 of Beecham);

(c) collecting of a sample, sample information, and personal information by the investigator sites (col. 1, lines 47-49 and col. 4, lines 32-43 of Beecham);

(d) submitting the sample, sample information and personal information by the investigator site to the third party, wherein the sample, sample information and personal information are coded with a first code (col. 4, lines 52-63 and col. 11, lines 22-27 of Beecham);

(e) associating a second code with the sample, sample information and personal information, wherein the associating is done by the third party (col. 11, lines 22-33 of Beecham);

(f) submitting the sample and sample information to the researcher by the third party (col. 4, lines 44-46 of Beecham); and

(g) storing of the personal information by the third party (col. 14, lines 28-45 of Beecham).

(H) Referring to claim 8, Beecham discloses wherein the first code is provided by the researcher (col. 4, lines 44-52 and col. 14, lines 43-49; the Examiner interprets “remote site for testing and analysis” to be a form of “researcher”).

(I) Referring to claim 9, Beecham discloses wherein the first code is provided by the third party (col. 4, lines 32-43 and col. 17, lines 20-28; the Examiner interprets “Planned Parenthood” to be a form of “third party”).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches a system for tracking secure medical test cards (5,612,870); an interactive remote sample analysis system (US 6,192,320 B1); a genetic profiling and banking system and method (US 6,640,211 B1); a medical privacy system (5,325,294); a method and system for anonymously testing a human malady (5,978,466); and an Internet autopsy database (<http://www.autopsydb.org/consent.htm>).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is (703) 305-0260. The examiner can normally be reached on Monday - Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703) 305-9588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LN

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1-3-05

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